IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF TEXAS

CHILDREN'S HEALTH DEFENSE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 6:22-cv-00093
	)	
FOOD and DRUG ADMINISTRATION, *et al.*	)	
	)	
Defendants.	)	
_____	)	

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR A STAY

TO THE HONORABLE JUDGE OF THE COURT:

COME NOW Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, and Sacha Dietrich reply in support of their motion to stay.

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I. INTRODUCTION

Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, and Sacha Dietrich ask this Court to grant their Motion to Stay ("Motion") the FDA's Emergency Use Authorization ("EUA") for Pfizer-BioNTech's COVID-19 vaccine for children ages five through eleven. Plaintiffs have shown irreparable injury, likelihood of success on the merits, and that the requested temporary injunctive relief is in the public interest. As such, this Court should grant Plaintiffs' Motion to Stay the FDA's EUA for Pfizer's COVID-19 vaccine for children ages 5-11 until such time as this Court can properly review Plaintiffs' claims.

II. PLAINTIFFS HAVE MET THEIR BURDEN FOR THE COURT TO ISSUE A MOTION TO STAY

a. 5 U.S.C. § 705 Authorizes Plaintiffs Requested Relief

The APA, pursuant to 5 U.S.C. § 705, directly authorizes the relief Plaintiffs seek.

Defendants argue that the relief Plaintiffs request is not permitted under 5 U.S.C. § 705. However, the relief they request here is exactly the type of remedy that § 705 allows. A stay of the FDA's EUA falls under the second remedy available under § 705: "to preserve status or rights pending conclusion of the review proceedings." Section 705 provides that the reviewing court "may issue all necessary and appropriate process" to do so to "the extent necessary to prevent irreparable injury." *Id.*

Defendants further claim that Plaintiffs are seeking to *alter* the status quo rather than to maintain it. Defendants argue that because the EUA was in effect at the time Plaintiffs Complaint was filed, allowing children between 5-11 to receive the Pfizer-BioNTech EUA vaccine qualifies as the "status quo." Opp. Mtn. to Stay, 5. This is blatantly false. Under FDA's logic, the Court would be unable to take any action to alleviate Plaintiffs' harm pending judicial review.

The Fifth Circuit imposes no such higher burden on Plaintiffs seeking a mandate rather than a stay. There is no "particular magic in the phrase 'status quo.' " *Canal Auth. Of Fla. v. Callaway,* 489 F.2d 567, 576 (5th Cir. 1974) ("*Callaway")*. In *Callaway,* the court stated the preliminary injunction analysis must focus on the "prevention of injury by a proper order, not merely on preservation of the status quo." "If the currently existing status quo itself is causing one of the parties irreparable injury, it is necessary to alter the situation so as to prevent the injury . . . by returning to the last uncontested status quo between the parties by the issuance of a mandatory injunction." *Id.* (internal citations omitted).

The FDA has previously attempted this same flawed argument. *Wages and White Lion Investments, L.L.C. v. United States Food and Drug Administration,* 16 F.4th 1130 (5th Cir. 2021). In that case, the Fifth Circuit rejected the FDA's claim that the Court lacked authority to grant a stay that provided "interim relief" when the plaintiff "merely seeks to preserve the *status quo ante,* before the FDA issued the Order." *Id.* at 1144. Just as the FDA's argument failed there, so must it fail here. Plaintiffs are entitled to seek relief that would "simply suspend *administrative* alteration of the status quo" as it is "long recognized that such temporary relief from an administrative order . . . is considered a stay." *Nken v. Holder,* 556 U.S. 418, fn. 1, 129 S. Ct. 1749, 173 L. Ed. 2d 550 (2009). Defendants' definition of "status quo" would only allow Plaintiffs' injuries to persist.

Finally, Defendants argue that such a remedy would not "preserve" Plaintiffs' "rights." 5 U.S.C. § 705; Opp. to Mtn. to Stay, 6. Defendants focus entirely on Plaintiff Deborah L. Else's and Sacha Dietrich's purported choice to not vaccinate their children. This argument neglects the mandates that are already occurring because of this EUA and the concerted efforts to permit minors as young as 11 to exercise "informed consent" without parental involvement at all. The

stay pending full judicial inquiry would preserve Plaintiffs' rights to informed consent and their children's equal access to education and medical care.

III. PLAINTIFFS HAVE MET EVERY FACTOR REQUIRED FOR INJUNCTIVE RELIEF

a. Plaintiffs Have Established Jurisdiction

i. All Plaintiffs Enjoy Article III Standing

Contrary to FDA's assertions, this Court has jurisdiction because each Plaintiff has an individual right to standing. As Plaintiffs will address more thoroughly in their response to Defendants' Motion to Dismiss, CHD enjoys both organizational and associational standing and thus can sue on behalf of itself and its members.

An organization has Article III standing in its own right if it is able to allege injury to its organizational activities and a consequent drain on its resources. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378 (1982). Expenses associated with litigation that a plaintiff organization is required to expend in pursuing a lawsuit are a drain on organizational resources sufficient to establish the organization's standing.

Here, the allegations in the Complaint sufficiently pleaded that Plaintiff CHD satisfies this threshold. First, CHD's Citizen Petition, filed May 16, 2021, was the result of countless hours of work and effort by CHD personnel, including but not limited to Meryl Nass, M.D. (Scientific Advisory Board member) and Robert F. Kennedy, Jr. (Board Chair and Chief Litigation Counsel), requesting that the FDA revoke the EUAs for existing COVID-19 vaccines and refrain from licensing them. Complaint, ¶ 39. Additionally, the Citizen Petition assembled and referenced a tremendous amount of detailed factual findings and research regarding the vaccines' risks to public health and safety and effectiveness (or lack thereof), the FDA's misbranding of the vaccine authorizations, and the serious injuries and consequences spawned by the FDA's

actions to CHD members and their children. CHD has and continues to divert substantial resources, time, and manpower from its current activities to the threat the FDA's authorization poses to millions of children, a risk that CHD has been warning about for months. Such resource diversion is, itself, grounds for standing. *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1303 (2017).

CHD also has associational standing to bring suit because the organization has demonstrated that "(1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and, (3) neither the claim asserted nor the relief requested requires the participation of individual members." *Texans United for a Safe Econ. Educ. Fund v. Crown Cent. Petroleum Corp.*, 207 F.3d 789, 792 (5th Cir. 2000).

Plaintiffs Deborah L. Else and Sacha Dietrich also each satisfy Article III standing requirements ("a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181, 120 S. Ct. 693, 145 L.Ed. 2d 610 (2000) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-561, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992)). Plaintiffs' children have been subject to continuous advertisements, pressure, and coercive tactics to encourage them to take the EUA COVID-19 vaccine. Their children face the risk of expanding vaccine mandates, including those preventing them from receiving life-saving transplants and medical treatment. This injury, outlined in detail in Plaintiffs' declarations filed along with their Motion to Stay, is both concrete and particularized, and actual and imminent. The injury sustained by Plaintiffs and their children stems directly from FDA's illicit

authorization and the false misrepresentation that this biologic is a "vaccine" that has been adequately tested for safety and confers benefit to children.

ii. Defendants Cannot Escape Judicial Review by Claiming Sovereign Immunity

Defendants incorrectly argue that the FDA enjoys sovereign immunity and that Plaintiffs' causes of action are beyond the APA's scope of review. Opp. Mtn. to Stay, 7. The APA § 702 presents two requirements for establishing a waiver of sovereign immunity: (1) the plaintiff must "identify some 'agency action' affecting him in a specific way, which is the basis of his entitlement for judicial review," *Alabama-Coushatta Tribe of Texas v. United States*, 757 F.3d 484 (5th Cir. 2014) (quoting 5 U.S.C. § 702), and (2) the plaintiff must demonstrate that she has "suffered legal wrong because of the challenged agency action, or is adversely affected or aggrieved by that action within the meaning of a relevant statute." *Lujan,* 497 U.S. at 883. Plaintiffs satisfy these criteria.

Exemptions from judicial review are rare and "not generally to be 'liberally construed.'" *United States v. Nordic Vill. Inc.*, 503 U.S. 30, 34, 112 S. Ct. 1011, 117 L. Ed. 2d 181 (1992). There is a "'strong presumption' that Congress intends that the federal courts review agency action." *Lundeen v. Mineta*, 291 F.3d 300, 305 (5th Cir. 2002). FDA authorizations and approvals are not actions that are "traditionally committed to agency discretion." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2568, 204 L. Ed. 2d 978 (2019). There is no applicable exemption or exception here.

b. Plaintiffs' Motion to Stay Demonstrates a Substantial Likelihood That They Will Ultimately Prevail on the Merits

When FDA granted an EUA for the Pfizer-BioNTech COVID-19 mRNA biologic for young children ages 5-11 they willfully ignored the overwhelming data, scientific studies, and

case reports indicating not only that the risks of the COVID-19 injections to children were significantly higher than the benefits, but also that it was wholly unnecessary to vaccinate these children. Defendants fast-tracked a biologic via an authorization process reserved for the most emergency and extreme circumstances. The FDA has exceeded the scope of its authority under the emergency use authorization statute in authorizing this vaccine for young children. There is no former or current emergency for children ages 5-11 from COVID-19 they have a statistical zero risk of death from SARS-CoV-2 infection. FDA has abused its discretion in authorizing the vaccine to this age group.

Plaintiffs have successfully demonstrated both in their Complaint and in their Motion to Stay that they have a valid cause of action against Defendants. Plaintiffs have shown Defendants violated 5 U.S.C. § 706 by failing to follow APA rules and limitations of authority and arbitrarily and capriciously granted an EUA for Pfizer-BioNTech's covid-19 biologic for these children.

Defendants' violation of the APA is twofold: (1) the FDA exceeded the scope of its authority by authorizing a biologic for emergency use only when it had no reasonable rationale to do so; and (2) the FDA acted arbitrarily and capriciously when granting this EUA by failing to engage in reasoned decision-making. Under the APA's arbitrary and capricious standard of review, the Court must "ensure that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Wages*, 16 F.4th at 1136 (quoting *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158, 209 L. Ed. 2d 287 (2021)); *see* 5 U.S.C.A. § 706(2). Agency action that is "premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment" must be set aside. *Id.*

The FDA acted outside its scope of authority when it authorized a biologic under the emergency use statute, 21 U.S.C. § 360bbb-3, when no "actual" or "potential" emergency existed to this age group. The FDA acted arbitrarily and capriciously, and certainly outside the zone of reasonableness, by failing to examine and consider a totality of the evidence when making its determination to authorize such a biologic.

c. Plaintiffs Will Suffer Irreparable Harm if a Motion to Stay is Not Granted

"To satisfy the second element of the preliminary injunction standards, the [Plaintiff] must demonstrate that if the district court denied the grant of a preliminary injunction, irreparable harm would result." *Janvey v. Alguire*, 647 F.3d 585, 600 (5th Cir. 2011). A harm is irreparable when there is "no adequate remedy at law, such as monetary damages." *Id.*

Plaintiffs' Motion to Stay references declarations from Plaintiffs Deborah L. Else and Sacha Dietrich, and from Mary Holland, CHD president and general counsel, that detail the imminent and irreparable harm faced because of the FDA's 5-11 EUA. Loss of bodily autonomy, forfeiture of conscience, loss of informed consent are all forms of irreparable harm. The ostracism, discrimination, and denial of medical treatment facing unvaccinated children is irreparable harm. These threats cannot be allowed to continue. Furthermore, monetary damages would not be an adequate remedy as they would not address any of the harms Plaintiffs assert.

Defendants argue that the delay between Plaintiffs' filing the Complaint and Motion to Stay precludes them from being able to request injunctive relief. However, "[c]ourts permit delays when determining the imminence of alleged irreparable harm where delays were 'caused by [plaintiff's] good faith efforts to investigate facts and law.' " *ADT, LLC v. Cap. Connect, Inc.*, 145 F. Supp. 3d 671, 699 (N.D. Tex. 2015) (quoting *Marks Organization, Inc. v. Joles*, 784 F.Supp.2d 322, 333–34 (S.D.N.Y.2011)). "[D]elay will not negate a finding of irreparable harm

where the plaintiff has a good explanation." *Daily Instruments Corp. v. Heidt,* 998 F. Supp. 2d 553, 570 (S.D. Tex. 2014).

The period between the filing of Plaintiffs' Complaint and Motion to Stay is a matter of months, hardly a delay sufficient to justify the denial of such an essential remedy against the harms Plaintiffs face. The full consequences of FDA's actions were not immediately evident after it granted the EUA. Due to the poor performance of Pfizer's vaccine for individuals 12 and older, Plaintiffs could not have reasonably anticipated the level of discrimination they and their children would face because of being unvaccinated. They were not immediately aware of the medical discrimination occurring in hospitals in several states, including Texas, where there are at least two confirmed reports of the denial of life-saving organ transplants to children as young as five based on vaccination status. After witnessing this life-threatening discrimination against children, Plaintiffs demonstrated "reasonable diligence" in requesting a motion to stay after careful evaluation of recent science and cases of discrimination. *Benisek v. Lamone*, 138 S. Ct. 1942, 1944, 201 L. Ed. 2d 398 (2018). Furthermore, delay is only a "single factor in the irreparable-harm balancing inquiry." *Advanced Commc'n Design, Inc. v. Premier Retail Networks, Inc.*, 46 F. App'x 964, 984 (Fed.Cir. 2002).

d. The Threatened Injury to Plaintiffs Outweighs Any Damage the Proposed Injunction May Cause the FDA & Public Interest Requires the FDA to Protect Against Unreasonably Dangerous Experimental Products

When the government is the opposing party, the third and fourth requirements of a preliminary injunction, the balance of equities and public interest, merge and may be considered together. *Texas v. Becerra*, No. 2:21-CV-229-Z, 2021 WL 5964687 *16 (N.D. Tex. Dec. 15, 2021); *see also Nken*, 556 U.S. at 435.

There is no harm to Defendants caused by granting the Motion since all Plaintiffs are merely asking this Court to make Defendants follow the law, act within the scope of their authority, and adhere to their purpose of protecting the American people, and importantly children, from harmful pharmaceutical products. This is in the public interest.

A stay would not alter the authorizations or licensure of COVID-19 vaccines for other age cohorts, who are demonstrably far more at risk from COVID-19 than children ages 5-11. The requested relief would merely force Defendants to adhere to their traditional practices and safety precautions that they have wantonly disregarded here, thus preventing potentially catastrophic and life-altering consequences from vaccine mandates by government, schools, businesses, and medical care facilities.

On the other hand, the injury to Plaintiffs should the Motion be denied is substantial. The palpable danger that their children will be denied medical care and access to education outweighs any benefit an experimental vaccine may have to "save" children from a disease that poses virtually no risk of death to them. Plaintiffs are not free to make this important vaccination choice without consequence. Defendants fail to address the coercion to take the shot, ostracism, the misrepresentation of safety, the potential denial of access to education and societal benefits, and the refusal of life-saving medical treatment, that unvaccinated children in Texas now face.

Further, granting the injunction "will not disserve the public interest." *ADT*, 145 F. Supp. 3d at 681. There is no public interest in a dangerous, improperly tested, experimental mRNA vaccine being foisted on children. It is the FDA's role to prevent such harmful biologics from being administered to *any* individual. The FDA was established to prevent the public from being subjected to harmful drugs. The public's interests are best served by ensuring that all vaccines on the market rise to a reasonable level of safety and effectiveness, as the public has come to expect

from the FDA. The FDA has abused people's faith in its determinations, putting all children, vaccinated or unvaccinated, at risk.

The balance of equities and the public interest weigh in favor of granting Plaintiffs' Motion to Stay FDA's EUA for children ages 5-11 as a proper remedy under § 705.

IV. CONCLUSION

Given the grave nature of the injury and substantial risk this EUA poses, Plaintiffs meet the criteria required to warrant such emergency judicial action until the merits of Plaintiffs' claims may be properly resolved.

For the foregoing reasons, the Court should grant Plaintiffs' Motion to Stay the Pfizer-BioNTech's EUA for children ages 5-11 pending judicial review.

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Respectfully submitted,

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